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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/520,963 | 08/26/2005 | Peter H Seeberger | MTV-055.01 | 4931 |

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| EXAMINER | |
|---|---|
| HENRY, MICHAEL C | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1623 | |

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|---|---|
| 09/20/2007 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/520,963 | SEEBERGER ET AL. | |
| | Examiner | Art Unit | |
| | Michael C. Henry | 1623 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,3-11 and 13-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-9, 11, 19-30* is/are rejected.

7)☐ Claim(s) *3, 10, 13-18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

The following office action is a responsive to the Amendment filed, 06/15/07.

The amendment filed 06/15/07 affects the application, 10/520,963 as follows:

1. Claims 1, 10, 11, 18, 19, 27, 30 have been amended. Claims 2, 12 have been canceled.

The responsive to applicants' amendments is contained herein below.

Claims 1, 3-11, 13-30 are pending in application

### *Claim Objections*

Claims 10, 18, 30 are objected to because of the following informalities: The claims contain chemical structures, which contains representative letters of the groups attached to the rings of the said chemical structures. However, these groups are not legible. Appropriate correction is required.

Claim 17 is objected to because of the following informalities: Claim 17 does not end in with a period. However, each claim should begin with a capital letter and end with a period. See Fressola v. Manbeck, 36 USPQ2d 1211 (D.D.C. 1995). Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites the phrase "combining". However, the claim is indefinite because it is unclear how said compounds are combined with each other as opposed to how the compounds are made to react. Consequently, the claim is indefinite and, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 27 recites the phrase "binding a mannopyranose to a solid support". However, the claim is indefinite because it unclear how said mannopyranose is bound to said support.

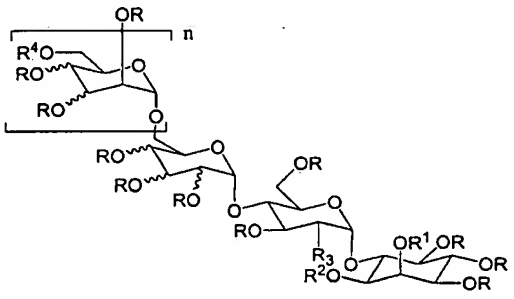
***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6, 8, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaworek et al. (Carbohydrates Research 331 (2001) 375-391).

In claim 1, applicant claims a compound represented by formula I:



I

wherein,

n is 1, 3 or 4;

R represents independently for each occurrence H, alkyl, aryl, -$CH_2$-aryl, -C(O)-alkyl, -C(O)-aryl, or -Si(alkyl)$_3$;

$R^1$ and $R^2$ are independently H, -$CH_2$-aryl, -C(O)-alkyl, -C(O)-aryl, -Si(alkyl)$_3$; or $R^1$ and $R^2$ taken together are $C(CH_3)_2$, P(O)OH, or P(O)$OR^5$;

$R^3$ is amino, -$N_3$, or -$NH_3X$;

$R^4$ represents independently for each occurrence H, alkyl, aryl, -$CH_2$-aryl, -C(O)-alkyl, -C(O)-aryl, -Si(alkyl)$_3$, or -P(O)$(OR^5)_2$;

$R^5$ represents independently for each occurrence H, $Li^+$, $Li^+$, $Na^+$, $K^+$, $Rb^+$, $Cs^+$, aryl, or an optionally substituted alkyl group; and

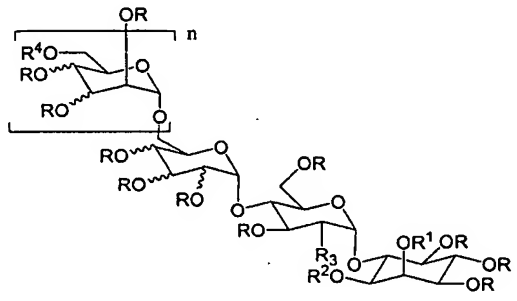
X is a halogen, alkyl carboxylate, or aryl carboxylate.

Jaworek et al. disclose applicant's compound of formula I wherein n = 1; R = H; $R^1$ and $R^2$ taken together is P(O)OH; $R^3$ = amino; $R^4$ = H (see compound 3, page 376). It should be noted that although compound 3 is represented with $R^3 = NH_3^+$ and $R^1$ and $R^2$ taken together = $P(O)O^-$ this compound is the same as applicant's compound wherein $R^1$ and $R^2$ taken together is P(O)OH and $R^3$ = amino (i.e., -$NH_2$) since at a given pH (probably in pure water) the $O^-$ on the $P(O)O^-$ group will be protonated to give P(O)OH and $NH_3^+$ will be deprotonated to give the amino (i.e., -$NH_2$). That is, Jaworek et al. compound is the same as applicant's claimed compound but is represented in it's zwitterion form. Claim 4 which is drawn to the compound of claim 1, wherein R is H, is also anticipated by Jaworek et al., since in Jaworek et al.'s compound R is H (see compound 3, page 376). Claim 5 which is drawn to the compound of claim 1, wherein $R^1$ and $R^2$ taken together is P(O)$OR^5$, is also anticipated by Jaworek et al., wherein $R^5$ (see compound 3, page 376). It should be noted that although compound 3 is represented with $R^3 = NH_3^+$ and $R^1$ and $R^2$ taken together = $P(O)O^-$ this compound is the same as applicant's compound wherein $R^1$

and $R^2$ taken together is P(O)OH and $R^3$ = amino (i.e., $-NH_2$) since at a given pH (probably in pure water) the $O^-$ on the $P(O)O^-$ group will be protonated to give P(O)OH and $NH_3^+$ will be deprotonated to give the amino (i.e., $-NH_2$). That is, Jaworek et al. compound is the same as applicant's claimed compound but is represented in it's zwitterion form. Claims 8 and 9 which are drawn to the compound of claim 1, wherein $R^4$ = H ...., is also anticipated by Jaworek et al., since $R^4$ = H, for Jaworeket al.'s compound (see compound 3, page 376). Claim 6 which is drawn to the compound of claim 1, wherein $R^3 = N_3$, is anticipated by Jaworek et al. (see compound 30b, page 380). It should be noted that in Jaworek et al.'s compound 30b, n is 1 and independentlyl R= $-CH_2$-aryl = $-CH_2$-phenyl = Bn, where Bn = benzyl and R = H (see compound 30b, page 380).

Claims 1, 3-5, 8, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin-Lomas et al. (Chem. Eur. J. 2000, 6, No. 19, pages 3608-3621).

In claim 1, applicant claims a compound represented by formula I:




I

wherein,

n is 1, 3 or 4;

R represents independently for each occurrence H, alkyl, aryl, -$CH_2$-aryl, -C(O)-alkyl, -C(O)-aryl, or -Si(alkyl)$_3$;

$R^1$ and $R^2$ are independently H, -$CH_2$-aryl, -C(O)-alkyl, -C(O)-aryl, -Si(alkyl)$_3$; or $R^1$ and $R^2$ taken together are $C(CH_3)_2$, P(O)OH, or $P(O)OR^5$;

$R^3$ is amino, -$N_3$, or -$NH_3X$;

$R^4$ represents independently for each occurrence H, alkyl, aryl, -$CH_2$-aryl, -C(O)-alkyl, -C(O)-aryl, -Si(alkyl)$_3$, or -$P(O)(OR^5)_2$;

$R^5$ represents independently for each occurrence H, $Li^+$, $Li^+$, $Na^+$, $K^+$, $Rb^+$, $Cs^+$, aryl, or an optionally substituted alkyl group; and

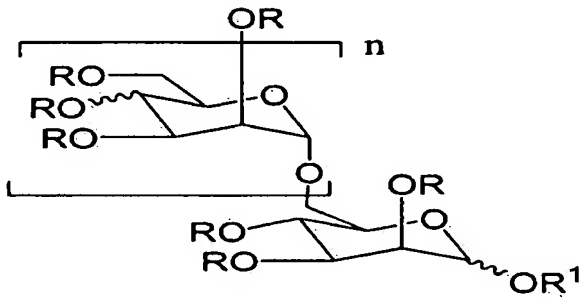
X is a halogen, alkyl carboxylate, or aryl carboxylate.

Martin-Lomas et al. disclose applicant's compound of formula I wherein n = 3; R = H; $R^1$ and $R^2$ taken together is P(O)OH; $R^3$ = amino; $R^4$ = H (see compound 2, page 3609). It should be noted that although compound 2 is represented with $R^3 = NH_3^+$ and $R^1$ and $R^2$ taken together = $P(O)O^-$ this compound is the same as applicant's compound wherein $R^1$ and $R^2$ taken together is P(O)OH and $R^3$ = amino (i.e., -$NH_2$) since at a given pH (probably in pure water) the $O^-$ on the $P(O)O^-$ group will be protonated to give P(O)OH and $NH_3^+$ will be deprotonated to give the amino (i.e., -$NH_2$). That is, Martin-Lomas et al. compound is the same as applicant's claimed compound but is represented in it's zwitterion form. Claim 3 which is drawn to the compound of claim 1, wherein n is 3, is also anticipated by Martin-Lomas et al., since in Martin-Lomas et al.'s compound n is 3 (see compound 2, page 3609). Claim 4 which is drawn to the compound of claim 1, wherein R is H, is also anticipated by Martin-Lomas et al., since in Martin-Lomas et al.'s compound R is H (see compound 2, page 3609). Claim 5 which is drawn to the compound of claim 1, wherein $R^1$ and $R^2$ taken together is $P(O)OR^5$, is also anticipated by Martin-Lomas et

al., wherein $R^5$ (see compound 2, page 3609). It should be noted that although compound 2 is represented with $R^3 = NH_3^+$ and $R^1$ and $R^2$ taken together = $P(O)O^-$ this compound is the same as applicant's compound wherein $R^1$ and $R^2$ taken together is P(O)OH and $R^3$ = amino (i.e., $-NH_2$) since at a given pH (probably in pure water) the $O^-$ on the $P(O)O^-$ group will be protonated to give P(O)OH and $NH_3^+$ will be deprotonated to give the amino (i.e., $-NH_2$). That is, Jaworek et al. compound is the same as applicant's claimed compound but is represented in it's zwitterion form. Claims 8 and 9 which are drawn to the compound of claim 1, wherein $R^4$ = H …., is also anticipated by Martin-Lomas et al, since $R^4$ = H, for Martin-Lomas et al.'s compound (see compound 2, page 3609).

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Kong et al. (CN 1297892) (Abstract Only).

In claim 11, applicant claims "A compound represented by formula II:




**II**

wherein,

n is 1, 3 or 4;

R represents independently for each occurrence H, alkyl, aryl, -$CH_2$-aryl, -C(O)-alkyl, -C(O)-aryl, or -Si(alkyl)$_3$;

$R^1$ is -$(CH_2)_mCH=CH_2$ or trichloroacetimidate; and

m is 1-6.

Kong et al. disclose applicant's compound of formula II wherein n = 3; R = H; $R^1$ and $R^2$ taken together is P(O)OH; $R^3$ = amino; $R^4$ = H (see compound 2, page 3609).

Rademacher et al. disclose applicant's compound of formula II wherein n = 1; R = aryl = -phenyl, and R = -C(O)-alkyl = -C(O)-methyl, and $R^1$ = trichloroacetimidate (trichloroethanimidate).

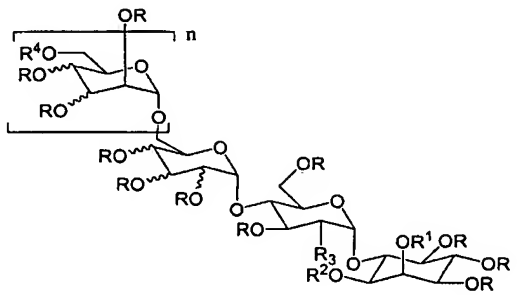
***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jaworek et al. (Carbohydrates Research 331 (2001) 375-391).

In claim 1, applicant claims a compound represented by formula I:




I

wherein,

n is 1, 3 or 4;

R represents independently for each occurrence H, alkyl, aryl, -$CH_2$-aryl, -C(O)-alkyl, -C(O)-aryl, or -Si(alkyl)$_3$;

$R^1$ and $R^2$ are independently H, -$CH_2$-aryl, -C(O)-alkyl, -C(O)-aryl, -Si(alkyl)$_3$; or $R^1$ and $R^2$ taken together are $C(CH_3)_2$, P(O)OH, or P(O)$OR^5$;

$R^3$ is amino, -$N_3$, or -$NH_3X$;

$R^4$ represents independently for each occurrence H, alkyl, aryl, -$CH_2$-aryl, -C(O)-alkyl, -C(O)-aryl, -Si(alkyl)$_3$, or -P(O)$(OR^5)_2$;

$R^5$ represents independently for each occurrence H, $Li^+$, $Li^+$, $Na^+$, $K^+$, $Rb^+$, $Cs^+$, aryl, or an optionally substituted alkyl group; and

X is a halogen, alkyl carboxylate, or aryl carboxylate.

Claim 7 is drawn to a compound of claim 1, wherein $R^3$ = -$NH_3X$.

Jaworek et al. disclose applicant's compound of formula I wherein n = 1; R = H; $R^1$ and $R^2$ taken together is P(O)OH; $R^3$ = amino; $R^4$ = H (see compound 3, page 376). It should be noted that although compound 3 is represented with $R^3 = NH_3^+$ and $R^1$ and $R^2$ taken together = $P(O)O^-$ this compound is the same as applicant's compound wherein $R^1$ and $R^2$ taken together is P(O)OH and $R^3$ = amino (i.e., -$NH_2$) since at a given pH (probably in pure water) the $O^-$ on the $P(O)O^-$ group will be protonated to give P(O)OH and $NH_3^+$ will be deprotonated to give the amino (i.e., -$NH_2$). That is, Jaworek et al. compound is the same as applicant's claimed compound but is represented in it's zwitterion form.

The difference between applicant's claimed compound and the compound taught by Jaworek et al. is that the applicant's compound is the ammonium halide salt (e.g., when X =$Cl^-$) of Jaworek et al.'s compound. However it is common in the art to prepare the salt form of a drug such as the ammonium halide salt of Jaworek et al.'s compound with the expectation that the salt form would have the same or even better pharmaceutical effect.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Jaworek et al., to have prepared a salt form of Jaworek et al.'s compound such as the ammonium halide salt, in order to use it to treat conditions such as malaria or diabetes since a skilled artisan would expect or predict that the salt form of Jaworek et al., compound would have the same or even better pharmaceutical or medicinal effect.

One having ordinary skill in the art would have been motivated to prepare a salt form of Jaworek et al.'s compound such as the ammonium halide salt, in order to use it to treat conditions such as malaria or diabetes based on factors such as availability and cost, since a skilled artisan would expect or predict that the salt form of Jaworek et al., compound would have the same or even better effect on said diseases or conditions.

***Allowable subject matter***

Claims 3, 10, 13-18 are objected to as being dependent upon a rejected base claim, but may be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Though the compounds of the present invention are similar to the compounds of the prior art, the compounds of claim 3, 10, 13-18 possess structural differences to the compounds of prior art documents and these differences are not suggested in the prior art, nor are obvious over the prior art. For example, the compounds of claims 3, 10, 13-

18 contain different numbers of monosaccharide residues and different types of functional groups or moieties attached to their pyranose rings as compared to the compounds of the prior art.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

9/4/07

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

September 3, 2007.